

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

REGINA MCMILLIAN, et al.,

Plaintiffs,

v.

SANOFI-AVENTIS U.S LLC,

Defendant.

Case No. 23-cv-05780-SI

**ORDER DENYING PLAINTIFF'S
MOTION FOR LEAVE TO FILE
AMENDED COMPLAINT**

Re: Dkt. No. 25

This case has been transferred to this Court from the Eastern District of Louisiana, where it was part of the multi-district litigation (“MDL”) *In re: Taxotere (Docetaxel) Products Liability Litigation*, MDL No. 2740. Plaintiff Regina McMillian now moves for leave to file an amended complaint. Dkt. No. 25. Pursuant to Civil Local Rule 7-1(b), the Court finds this matter appropriate for resolution without oral argument and VACATES the hearing set for March 15, 2024. For the reasons set forth below, the Court DENIES plaintiff’s motion.

BACKGROUND

This case is one of thousands filed against various defendants regarding the drug Taxotere (or Docetaxel, the generic version) and its alleged links to permanent hair loss. In her proposed “First Amended Complaint” (“FAC”), plaintiff alleges that Taxotere (Docetaxel) is a chemotherapy drug administered primarily to early-stage breast cancer patients. Dkt. No. 25-1 ¶ 3. Plaintiff alleges, “Defendant knew for years prior to Ms. McMillian’s use of Taxotere (Docetaxel) that it caused permanent hair loss. Yet, despite this knowledge, Defendant failed to warn Ms. McMillian and her treating physicians that Taxotere (Docetaxel) caused permanent hair loss.” *Id.* Plaintiff alleges that she now suffers from permanent hair loss as a result of her use of Taxotere (Docetaxel)

1 and that had she and her healthcare providers known that permanent hair loss could result from its
2 use, she would have chosen a different treatment option. *Id.* ¶ 4.

3 Plaintiff used Taxotere from approximately October 3, 2013, to December 5, 2013, as part
4 of her breast cancer treatment. *Id.* ¶¶ 7, 36. In the proposed FAC, plaintiff alleges that she “did not
5 learn that Taxotere (Docetaxel) causes permanent hair loss until sometime in late 2015 or 2016, well
6 within her two-year statute of limitations.” *Id.* ¶ 41. The proposed FAC further alleges that
7 “[p]laintiff did not suspect or have reason to suspect the tortious nature of Sanofi’s conduct causing
8 her injuries until late 2015 or early 2016 when seeing hearing [sic] about an advertisement.” *Id.*
9 ¶ 43.

10 On September 8, 2017, plaintiff filed suit in federal court as part of the MDL, using the
11 standard Amended Short Form Complaint then in effect in the MDL. *See* Dkt. No. 1 (“SFC”). Her
12 SFC incorporated by reference the Amended Master Long Form Complaint and Jury Demand filed
13 in the MDL on March 31, 2017. *Id.* at 1. She stated ten counts for liability. *Id.* at 4-5. These
14 included eight counts stated in the master complaint and two additional counts that plaintiff asserted
15 under California law.¹ *Id.* On October 16, 2017, defendants filed their Master Answer in the MDL.
16 Dkt. No. 6-4 at 246-341. In September 2018, plaintiffs filed a Second Amended Master Complaint,
17 which was “identical” to the prior master complaint but added two defendants. *See* Dkt. No. 6-2 at
18 151-52 (“Pretrial Order 82”) ¶ 2; *see also* Dkt. No. 6-4 at 342-411 (“Second Am. Master Compl.”).

19 In October 2019, plaintiffs filed a motion to amend the master complaint, seeking “to no
20 longer define their injury as manifesting six months after chemotherapy[,]” as the prior master
21 complaints had alleged. *In re Taxotere (Docetaxel) Products Liab. Litig.*, MDL No. 16-2740, 2020
22 WL 6888282, at *1 (E.D. La. Sept. 22, 2020) (citing MDL Dkt. No. 8334).² On December 11, 2019,
23 the MDL court denied the motion, “noting that the parties and the Court had been operating under
24

25 ¹ The two additional counts were for “Violations of Applicable California Law Prohibiting
26 Consumer Fraud and Unfair and Deceptive Trade Practices” and for loss of consortium. Dkt. No. 1
at 5.

27 ² The proposed amendments alleged that “[t]here is no single definition for Permanent
28 Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies
from patient to patient, including among Plaintiffs.” *In re Taxotere*, 2020 WL 6888282, at *1.

1 Plaintiffs’ original definition of their alleged injury for years.” *Id.* (citing MDL Dkt. No. 8702 at 3-
 2 4). The MDL court conducted an analysis under Federal Rule of Civil Procedure 15(a)(2) and
 3 determined that the amendment plaintiffs proposed “would be inappropriate at this time.” Dkt. No.
 4 6-4 at 1427. The court went on: “If the Court were to allow Plaintiffs to amend at this late stage,
 5 this would negate a significant amount of the work that has been done in this MDL. Defendants
 6 would undoubtedly want to revise certain expert reports and conduct supplemental depositions, and
 7 certain rulings from the Court would be mooted.” *Id.* at 1428. An “influx” of motions by individual
 8 plaintiffs to amend their short-form complaints then followed. *In re Taxotere*, 2020 WL 6888282,
 9 at *1 (citing MDL Dkt. Nos. 8703, 10338). The MDL court denied those motions that sought “to
 10 buttress their claims against statute-of-limitations defenses[,]” finding the amendments would
 11 prejudice defendants because defendants would need to conduct additional discovery and prepare a
 12 different statute-of-limitations defense. *Id.* (citing MDL Dkt. No. 8703).

13 On May 11, 2020, “to deal with the continuing flurry of motions, the Court issued Pretrial
 14 Order 105 (‘PTO 105’) to establish what kind of amendments are permissible and what kind are
 15 not.” *Id.* (citing MDL Dkt. No. 10338); *see also* Dkt. No. 6-2 at 167-68. Subtitled “Short Form
 16 Complaint Allegations and Amendments – Statute of Limitations Order,” PTO 105 allowed
 17 plaintiffs to “amend their complaints to add factual allegations regarding particularized facts
 18 individual and specific to each Plaintiff’s medical care and treatment and/or that Plaintiff’s
 19 communications with medical professionals.” Dkt. No. 6-2 at 167. PTO 105 set a deadline for
 20 plaintiffs to file amendments pursuant to the order, which the parties later stipulated to extend to
 21 January 15, 2021. *Id.* at 168-70. Ms. McMillian did not amend her short-form complaint.

22 On October 23, 2023, Judge Jane T. Milazzo signed an order transferring “Wave 2 Cases”
 23 from the MDL, including this one, back to the transferor districts. Dkt. No. 7. Judge Milazzo found
 24 “that the purposes behind consolidation have now been served. The Court has held two bellwether
 25 trials and has addressed numerous discovery disputes, dispositive motions, and other pretrial issues
 26 involving factual and legal questions common to all cases in this MDL proceeding.[] No further
 27 pretrial motions are pending in these cases, and transfer to the appropriate district courts appears to
 28 serve the interests of judicial efficiency.” *Id.* at 2. The transfer order also stated, “All deadlines for

1 Plaintiffs to amend their individual complaints without leave of court have passed.” *Id.* at 76 (citing
2 PTO 105). This case was transferred to this district on November 9, 2023. Dkt. No. 8.

3 On December 15, 2023, the undersigned held a case management conference during which
4 the parties raised the question of whether plaintiff should be allowed to amend the complaint now
5 that the case had returned to this district from the MDL. Dkt. Nos. 14, 21. The Court set a deadline
6 of January 26, 2024, for amendment of the pleadings. Dkt. No. 22. A jury trial is set for October
7 6, 2025.

8 Plaintiff now moves for leave to file the proposed FAC. Dkt. No. 25 (“Mot.”). The proposed
9 FAC names Sanofi-Aventis U.S. LLC as the defendant.³ In the proposed FAC, plaintiff seeks to
10 bring two claims for relief: (1) Negligence – Failure to Warn; and (2) Strict Products Liability –
11 Failure to Warn. Defendants oppose any amendment. Dkt. No. 28 (“Opp’n”). Plaintiff did not file
12 a reply brief, and the time to do so has now passed. *See* Civ. L.R. 7-3(c). Having considered the
13 record and the arguments of the parties, the Court now rules as follows.

14 **DISCUSSION**

15 **I. Legal Standard**

16 As a threshold matter, the parties dispute which legal standard the Court should apply.
17 Plaintiff assumes that the Court should apply Federal Rule of Civil Procedure 15(a)(2). *See* Mot. at
18 4. Defendants argue that plaintiff’s request should be denied for lack of good cause under Rule 16.
19 Opp’n at 12. Defendants further argue that plaintiff cannot meet the standard for amendment even
20 if the Court were to apply Rule 15. *Id.* at 12-13. The Court need not resolve this particular conflict,
21 as the Court agrees with defendants that plaintiff cannot meet the standard for amendment under
22 either Rule 15 or Rule 16.

23 Under Rule 15(a)(2), courts should “freely give leave [to amend] when justice so requires.”
24 Fed. R. Civ. P. 15(a)(2). Factors courts weigh in determining whether leave should be granted under
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26
27 ³ The opposition is filed on behalf of Sanofi U.S. Services, Inc. and sanofi-aventis U.S. LLC.
28 For purposes of today’s ruling, the Court will refer to “defendants” in the plural, to encompass these
two entities.

Rule 15(a)(2) include “the presence or absence of undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party and futility of the proposed amendment.” *Moore v. Kayport Package Exp., Inc.*, 885 F.2d 531, 538 (9th Cir. 1989) (citations omitted); *see also Hurn v. Retirement Fund Tr. of Plumbing, Heating & Piping Indus.*, 648 F.2d 1252, 1254 (9th Cir. 1981).

Under Rule 16(b)(4), a scheduling order may not be modified without a showing of “good cause.” Fed. R. Civ. P. 16(b)(4). The “good cause” requirement primarily considers the “diligence of the party seeking the amendment.” *Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 609 (9th Cir. 1992). While the degree of prejudice to the opposing party may “supply additional reasons to deny the motion, the focus of the inquiry is upon the moving party’s reason for seeking modification.” *Id.* If the party can show good cause, they must also demonstrate amendment is proper under Rule 15(a)(2). *Id.* at 608 (citing *Forstmann v. Culp*, 114 F.R.D. 83, 85 (M.D.N.C. 1987)).

II. Amendment of Pleadings

Defendants raise three main objections to plaintiff’s request to amend. First, they state that the proposed FAC does away with the definition of “injury” from the operative Master Complaint and thus would undo much of the MDL court’s work as well as years of discovery efforts.⁴ Defendants argue that the MDL court considered and rejected such a request for amendment, back in 2019. Opp’n at 7-8 (citing Dkt. No. 6-4 at 1427-29). Second, defendants argue this motion is far too late, where plaintiff did not amend her short-form complaint to add plaintiff-specific allegations regarding the statute of limitations when given the chance to do so in the MDL, via PTO 105. Third, defendants argue that plaintiff’s proposed amendments regarding punitive damages are not

⁴ The Second Amended Master Complaint alleged, “Unlike the temporary and reversible alopecia that ordinarily results from chemotherapy, Taxotere, Docetaxel Injection, and Docetaxel Injection Concentrate cause Permanent Chemotherapy Induced Alopecia, which is defined as an absence of or incomplete hair regrowth **six months beyond the completion of chemotherapy.**” Dkt. No. 6-4 at 377-78, ¶ 181 (emphasis added). The proposed FAC contains no analogous injury definition.

1 necessary under California law and so amendment would be futile. Plaintiff, by not filing a reply,
2 does not respond to any of these arguments.

3 Defendants also note that numerous courts in other districts have ruled against similar
4 attempts at amendment following transfer of Taxotere litigation from the MDL. Opp’n at 10 n.6,
5 11 n.7 (collecting cases); *see also Ali v. Sanofi-aventis U.S. LLC*, No. 3:23-cv-02694-JSC, 2023 WL
6 6390592, at *3 n.1 (N.D. Cal. Sept. 29, 2023) (at summary judgment stage, rejecting the plaintiff’s
7 offer to amend the master complaint to remove the six-month injury definition, where “in 2019, the
8 MDL court denied Plaintiff’s request for leave to amend their Long-Form Complaint in exactly this
9 way”).

10 Plaintiffs have not pointed to a single case in which a Taxotere plaintiff has been granted
11 leave to amend a complaint in a similar manner after remand from the MDL. In their case
12 management statement filed in December 2023, plaintiff cited three cases in other districts in which
13 courts set schedules allowing Taxotere plaintiffs to move for leave to amend their short form
14 complaints. Dkt. No. 14 at 5 n.2. Plaintiff neglected to mention in her statement that one of those
15 motions had already been denied. *See McClafin v. Sanofi-Aventis U.S. LLC*, No. 1:23-cv-01366-
16 CNS-MDB (D. Colo.), Dkt. Nos. 54 (Report & Recommendation, Nov. 13, 2023), 55 (Order
17 Adopting Report & Recommendation, Nov. 29, 2023).⁵ The other two district courts have also now
18 denied the motions to amend. *Fussell v. Sanofi US Servs., Inc.*, No. 1:23-cv-00142-MR-WCM
19 (W.D.N.C. Mar. 12, 2024), Dkt. No. 47 (Order); *Allain v. Sanofi-Aventis U.S. LLC*, No. 6:23-cv-
20 00992-CEM-RMN (M.D. Fla. Feb. 26, 2024), Dkt. No. 43 (Order).⁶

21 The Court tends to agree with defendants that plaintiff’s motion is less a motion to amend
22 the complaint than it is a motion for the Court to reconsider prior rulings in the MDL. This Court
23 is not inclined to do so. “A district judge exercising authority over cases transferred for pretrial
24 proceedings ‘inherits the entire pretrial jurisdiction that the transferor district judge would have
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26 ⁵ In *McClafin*, the Magistrate Judge denied the motion because it was inextricably
27 intertwined with the statute of limitations question the District Judge would need to resolve on
28 summary judgment. Thus, it was not a denial on the merits of the motion.

⁶ The plaintiffs in those three cases are represented by the same counsel that represents Ms. McMillian here.

exercised if the transfer had not occurred.” *In re Korean Air Lines Co., Ltd.*, 642 F.3d 685, 699 (9th Cir. 2011) (quoting 15 Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, *Federal Practice & Procedure* § 3866 (3d ed. 2010)). The Ninth Circuit has explained, “Such authority is broad and encompasses the power to decide dispositive pretrial motions.” *Id.* “Although the transferor judge has the power to vacate or modify rulings made by the transferee judge, subject to comity and ‘law of the case’ considerations, doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings.” Ann. Manual Complex Litig. § 20.133 (4th ed.) (citing Stanley A. Weigel, *The Judicial Panel on Multidistrict Litigation, Transferor Courts and Transferee Courts*, 78 F.R.D. 575, 577 (1978)). That the MDL court in this case already rejected proposals to remove the six-month injury definition, and that Ms. McMillian did not avail herself of the MDL court’s process for amending to allege plaintiff-specific facts (*see* PTO 105) weighs heavily against the granting of plaintiff’s present motion.

It may be that plaintiff refrained from moving for leave to amend in the MDL because she knew the attempt would not succeed. Here, for instance, she adds an allegation that she did not know that Sanofi’s conduct caused her injuries until she saw (or heard) an advertisement in late 2015 or early 2016. *See* Proposed FAC ¶ 43. The MDL court rejected identical attempts by individual plaintiffs to add allegations regarding when they saw advertisements linking Taxotere and permanent hair loss. *See In re Taxotere*, 2020 WL 6888282, at *4-5, *7-8. The Court cannot condone this attempted end-run around the MDL court’s rulings. And plaintiff’s lack of candor does not help her case. In her motion, she states that “there was a proverbial ‘pin’ put on this issue” of amendment. Mot. at 4. She does not reveal that the MDL court expressly denied, multiple times, attempts by plaintiffs to amend allegations in precisely the way plaintiff seeks to here.

Nevertheless, the Court is mindful that “when it comes to motions that can spell the life or death of a case, such as motions for summary judgment, motions to dismiss claims, or, as here, a motion to amend pleadings, it is important for the district court to articulate and apply the traditional standards governing such motions. A total disregard for the normal standards of assessing these critical motions would improperly subject MDL cases to different and ad hoc substantive rules.” *In re Korean Air Lines*, 642 F.3d at 700-01. Even analyzing plaintiff’s motion under the Federal Rule

of Civil Procedure 15(a)(2) standard, the Court finds that plaintiff’s motion should be denied. As other district courts in this litigation have determined post-remand, allowing plaintiff to amend her complaint at this late stage of the case would prejudice defendants, in that it would undo years of litigation and discovery efforts, necessitate the reopening of discovery, and create further delay. *See, e.g., Jackson v. Sanofi-Aventis U.S. LLC*, No. 3:23-cv-00553 (M.D. Tenn. Jan. 29, 2024), Dkt. No. 38 (Memorandum Opinion and Order). “Prejudice to the opposing party is the most important factor” under a Rule 15(a)(2) analysis. *Jackson v. Bank of Haw.*, 902 F.2d 1385, 1387 (9th Cir. 1990). Moreover, plaintiff cannot show that she did not engage in undue delay, where the MDL court set a deadline for plaintiffs to amend their short-form complaints with plaintiff-specific allegations, where the parties stipulated to an extension of that deadline, and where Ms. McMillian filed no amendment. *See Dunn v. Sanofi-Aventis U.S. LLC*, No. 3:23-cv-649-ECM, 2024 WL 314039, at *4 (N.D. Ala. Jan. 26, 2024) (“Because the Plaintiff has failed to amend her complaint in the six years that this case has been pending with no justification beyond the difficulty of working within a text box and pursuant to the MDL Court’s orders, the Court finds that the Plaintiff engaged in undue delay in filing her motion.”). Nor has plaintiff explained why she did not amend the complaint when given the chance to do so in the MDL.

Finally, defendants note that plaintiff adds further allegations regarding punitive damages. Opp’n at 14; *see also* proposed FAC at 13. Defendants argue such amendment is futile because “Ms. McMillian already incorporates the punitive damages allegations of the Second Amended Master Complaint into her SFC.” Opp’n at 14. Plaintiff does not explain why the additional allegations are necessary at this point. The Court agrees with defendants. In the Second Amended Master Complaint, “Plaintiffs seek both compensatory and punitive damages.” Dkt. No. 7 at 75; *see also* Dkt. No. 6-4 at 407. There is no need to amend the complaint at this stage to add a claim for punitive damages, where the operative complaint already seeks punitive damages.

As the other courts to have examined this issue have done, the Court DENIES plaintiff’s motion for leave to file an amended complaint.

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CONCLUSION

For the foregoing reasons, the Court DENIES plaintiff's motion for leave to file an amended complaint. A further case management conference remains on calendar for April 19, 2024, at 3:00 p.m. via Zoom videoconference. The parties' joint case management statement is due seven days in advance of the conference.

IT IS SO ORDERED.

Dated: March 13, 2024



SUSAN ILLSTON
United States District Judge